K030051

Premarket Notification (510K) Summary

APR 0 4 2003

Date Prepared: October 14, 2002

Submitter: Bionix Development Corporation
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Toledo, Ohio 43612
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Contact Person: James Huttner M.D., Ph.D.
[jjhuttner@yahoo.com (email)]

Trade Name: VersaBoard Patient Positioning System

Common Name: Carbon Fiber Patient Immobilization System

Classification Name: Medical charged-particle radiation therapy system, accessory (per CFR section 892.5050)

Intended Use: The VersaBoard from Bionix Development Corporation is designed to be used for the positioning and re-positioning of patients for receiving radiation therapy.

Claim of Substantial Equivalence:

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems.

One such device is the S-Type Baseplate manufactured and legally marketed by Med-Tec, Inc. of Orange City, Iowa. This device has been classified as a Class II device by the FDA, and has been granted marketing clearance and has been assigned the document control number K933227.

The S-Type Baseplate from Med-Tec consists of a flat "board" comprised of a composite material with a carbon fiber/epoxy skin and a foam core. The device has a generally torso-shaped contour, with a specific area for the head, shoulders, and back. The head portion contains in its center a mesh-like cutout section, where the carbon fiber/epoxy skin is bonded to itself with no foam core, and then a waffle-like cutout pattern is cut into the carbon fiber to give a more open area roughly where the patient's head should be. Other important features of the device are simple mechanical interlocking systems for attaching the S-Type Baseplate to the top of the radiation therapy couch, and for the attachment of contoured low-melt thermoplastic sheets that are used to further position and hold the patient.

The carbon fiber/epoxy/foam composite structure of the board has a minimal attenuation factor. This is due primarily to the foam core of the composite, which being mostly air blocks little of the radiation. Standard dosimetry has been used to document this fact, and such results have been widely published in the medical literature. The carbon fiber/epoxy skin provides strength and stiffness; in aggregate such composite structures are ideal for producing devices that reproducibly position patients and yet do not interfere with the administration of the therapeutic radiation. Patient positioning devices with this type of composite structure are common in radiation therapy. They come in many varieties and are manufactured by several companies; examples include Med-Tec, Aktina, Arplay, and Bionix.

In practice, the Med-Tec S-Type Base-plate is secured to the therapy couch tabletop either by a lock-down mechanism, or by the patient's own weight. The patient is positioned supine on the board with his head resting on a cradle over the area of the waffle cut-out, and then a mask of his/her upper torso is made by stretching warm low-melt thermoplastic over the patient, and then securing that mask to the board using the interlocking mechanism (in this case, custom panel-rivets) described earlier. As the low-melt thermoplastic cools it becomes rigid, taking and holding the shape of the patient. In this fashion the patient is positioned reproducibly on the board. Radiation therapy is then administered in the usual fashion. (Copies and marketing materials from the Med-Tec, Inc. catalog and web-site are appended to this document to substantiate and clarify the above claims as to design and use of the Med-Tec S-Type Baseplate.)

The Bionix VersaBoard is substantially equivalent to the Med-Tec S-Type Baseplate in design, construction, and function. The VersaBoard is flat and has a similar, generally torso-shaped contour, with an area specifically for the head, shoulders, and back. The head portion has a central open area where a thin plate of carbon fiber/epoxy is placed. This thin plate may have a waffle-like cutout, or a more sophisticated design that allows for the prone as well as supine positioning of the patient.

The Bionix VersaBoard is manufactured according to the FDA Good Manufacturing Practice guidelines using standard methods and practices. The VersaBoard is constructed in the same manner as the S-Type Baseplate from Med-Tec, having a carbon fiber/epoxy/foam core composite structure) that is an accepted standard in radiation therapy. The carbon fiber/epoxy again provides stiffness and strength, while the foam core allows for almost no attenuation of the radiation beam during the treatment process. The VersaBoard also has simple mechanical interlocks that allow the board to be secured to the tabletop of the therapy couch. Other interlocks or clamps allow low-melt thermoplastic to be attached to the VersaBoard during the patient positioning process. (Engineering drawings and perspective views, as well as digital images of the prototype device are appended to this document to substantiate the above claims as to design and structure of the Bionix VersaBoard, as production models are not yet available.)

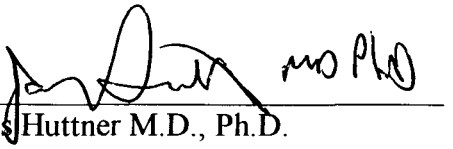
In clinical practice the VersaBoard again functions similarly to the Med-Tec S-Type Baseplate. The patient is positioned on the VersaBoard in either the prone or supine position, with his head resting on a foam cushion or support. Warm low-melt thermoplastic in its pliable state is then draped over the patient's head and shoulders

where it conforms to the patient's anatomy. It is then secured to the VersaBoard using clamps or other simple mechanical interlocks. When it cools, the low-melt thermoplastic becomes rigid and retains the shape of the patient, allowing him to be positioned and re-positioned securely during the radiation therapy regimen.

Based on the almost identical design and construction of the Bionix VersaBoard to the S-Type Baseplate currently manufactured and sold by Med-Tec, Inc., it is reasonable to expect that the two devices will have similar properties as regards to stiffness, support strength, and minimal attenuation of the radiotherapy beam, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the VersaBoard and the Med-Tec S-Type Baseplate are intended for use in positioning and re-positioning patients during radiation therapy procedures, and both boards are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the VersaBoard manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the S-Type Baseplate manufactured by Med-Tec, Inc.

The Bionix VersaBoard is also substantially equivalent to other similar patient positioning devices constructed from carbon fiber/epoxy/foam core composites. Two such devices are the Carbon Fiber Breast Board manufactured and legally sold by Med-Tec, Inc. of Orange City, Iowa (K974703), and the Max 2 Deluxe TorsoBoard manufactured and legally sold by Bionix Development Corp., Toledo, Ohio (K905007). Both the Carbon Fiber Breast Board from Med-Tec and the Max 2 Deluxe TorsoBoard from Bionix are intended to be used to accurately position and hold patients securely during a radiation therapy treatment regimen. Both of these devices are constructed from carbon fiber/epoxy/foam core composites that produce minimal attenuation to the radiotherapy beam, similar to that exhibited by the VersaBoard. These devices also contain or use simple mechanical interlock mechanisms to secure the boards to the treatment couch tabletop, and others that secure low-melt thermoplastic to the boards themselves, allowing the low-melt thermoplastic to be formed into a mask that contours to the patient and can be used to accurately position and hold the patient during the radiation therapy procedure. In like fashion, the VersaBoard is intended to accurately position and securely hold patients undergoing radiation therapy. The VersaBoard has similar mechanical interlock mechanisms to secure the board to the therapy couch tabletop and to low-melt thermoplastic, as described above.

The almost identical design, construction, materials, properties, performance and intended use of the VersaBoard to the Carbon Fiber Breast Board from Med-Tec and the Max 2 Deluxe TorsoBoard form Bionix Development Corp., both existing legally sold devices, prove the Bionix VersaBoard to be substantially equivalent to these devices as well.

Submitted by: 

James Huttner M.D., Ph.D.
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Bionix Development Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 4 2003

James Huttner, M.D., Ph.D.
Vice President, New Product Development
Bionix Development Corporation
5154 Enterprise Blvd.
TOLEDO OH 43612

Re: K030051
Trade/Device Name: Versaboard Patient Positioning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charge-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: October 15, 2002
Received: January 6, 2003

Dear Dr. Huttner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): K030051

Device Name: VersaBoard Patient Positioning System

Indications for Use:

The VersaBoard patient positioning system developed and manufactured by Bionix Development Corporation, Toledo, Ohio, is intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Optional Format 3-10-98)

(Posted July 1, 1998)

Back to the Indications for Use Page

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030051